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Reducing suicidality in autism-spectrum patients using dialectical behaviour therapy

Submission date
19/04/2019

Recruitment status
No longer recruiting

Registration date
01/05/2019

Overall study status
Completed

Last Edited
03/06/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many patients with autism spectrum disorder are treated in long-term specialized care, and suicidal behaviour is an issue that troubles patients, families and specialists in the field and is difficult to treat. At this moment, there is no documented effective therapy for suicidal behaviour in ASD. Dialectical Behaviour Therapy is an efficacious treatment program for chronically impulsive suicidal and/or self-harm behaviour in patients with Borderline Personality Disorder and this study will evaluate the efficacy of Dialectical Behaviour Therapy in patients with an autism spectrum disorder and suicidal behaviour in a randomised controlled trial.

Who can participate?
Patients with autism spectrum disorder, suicidal and/or self-harming behaviour, aged 18 - 65 years

What does the study involve?
The study is the first to test a treatment protocol aimed at reducing self-harm and suicidal behaviour in people with autism spectrum disorder.

What are the possible benefits and risks of participating?
The aimed for benefits are more self-control over strong emotions such as despair and anger and control over self-harm and other suicidal behaviour and suicide attempts.
The medical ethical committee judged the study as “no-increased risk”. The patient can stop the participation in the trial at any moment, without any consequences for the treatment.

Where is the study run from?
1. Parnassia Psychiatric Institute, The Hague, Netherlands
2. Antes Psychiatric Institute, Rotterdam, Netherlands
3. Rivierduinen psychiatric institute, Leiden, Netherlands
4. Lentis psychiatric institute, Groningen, Netherlands

When is the study starting and how long is it expected to run for?
August 2018 to January 2023 (updated 20/05/2021, previously: January 2022)

Who is funding the study?
Stichting tot Steun VCVGZ (Foundation for VCVGZ Support), Netherlands

Who is the main contact?
1. Prof. Mark van der Gaag (scientific contact), m.vander.gaag@vu.nl
2. Mrs Anne Huntjens (scientific contact), a.huntjens@parnassia.nl

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NL59497.029.17

Study information

Scientific Title
The effect of dialectical behaviour therapy in autism-spectrum patients with suicidality and/ or self-destructive behaviour: a multi-site randomized controlled trial

Acronym
DIASS

Study objectives
The primary objective is to evaluate the effect of a short term DBT treatment program (26 weeks) versus treatment as usual, in terms of reduction of suicidal and/or self-harming behaviour in adult outpatients with autism.
A. Other objectives were to determine the efficacy of DBT versus TAU on (a) anxiety, (b) social performance, (b) depression, (c) core symptoms of ASD and (d) quality of life. The DBT dairy card is an assessment technique designed to obtain repeated self-reports.
B. An economic evaluation will determine the cost-effectiveness and cost-utility of the DBT treatment
C. In the intervention study, we will conduct additional research to explore mechanisms of changes in the treatment outcome variables. Variables that are potential predictors, mediators and moderators will be examined, such as: a) emotion regulation; b) strength of the therapeutic alliance; c) difficulties engaging in goal-directed behaviours; d) demographic characteristics; e) alexithymia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2018, Medical Ethics Committee of VU Medical Centre Amsterdam (METc VUmc : BS7, room H-443, P.O Box 7057, 1007 MB Amsterdam, the Netherlands; +31 20 44 45 58 5; metc@vumc.nl), ref: 2017.547 NL59497.029.17

Study design
Single-blind multi-site randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Suicidal ideation, self-harm and suiciadal behaviour in patients with autism-spectrum disorder

Interventions

The study design is a multicentre single-blind randomized controlled trial with two arms. The experimental arm is Dialectical Behaviour Therapy and the active control arm is individual psychotherapy.

The study population are 128 adult outpatients with autism spectrum disorder with suicidal and /or self-harming behaviour in the last year.

The DBT consists of weekly individual cognitive–behavioural therapy sessions and group skills-trainings two times each week during 2.5 hours per session. The order of the topics of each session is based on Linehan's protocol and is pre-determined: suicidal and self-destructive behaviour, therapy interfering behaviour, quality of life interfering behaviour and generalization of the skills taught in the training. Each therapy session starts with the diary cards that hold all the information concerning the problematic behaviours which are the primary goal of the treatment, but also behaviours that influence the primary goals (such as alcohol and drug use, the urge to self-harm, substance abuse, dissociation, level of applied skills). The skills-training groups lasting 2.5 h per and there are two sessions each week. The skills taught are standard DBT skills and combine self-regulation and change skills, and skills for self-acceptance and acceptance of others: Core mindfulness skills, Interpersonal effectiveness skills, Emotion regulation skills, Crises skills and Radical acceptance. Missed meetings need to be caught up by watching the video recordings that are made of all the training sessions

The control condition is psychotherapy each week. This is a needs-based intervention with shared decision making between the patient and the psychotherapist.

The experimental period is six months.

Randomization is conducted by the independent randomisation bureau of Parnassia Psychiatric Institute with the use of block randomisation with the randomisation software from www. randomizer.org. Research Randomizer (Version 4.0).

Intervention Type
Behavioural

Primary outcome(s)
Suicidal ideation measured by the 'Suicidal Ideation Attributes Scale' and self-harm and suicidal behaviour as measured by the 'Lifetime Parasuicide Count'.

Key secondary outcome(s))
1. Social Anxiety (Social Interaction Anxiety Scale)
2. Depression (Beck Depression Inventory-2)
3. Quality of Life (Manchester Short Assessment of Quality of Life)
4. Social functioning (Personal and Social Performance Scale)
5. Autism symptoms (Autism Spectrum Quotient-28 & Social Responsiveness Scale)
6. Emotion Regulation {Difficulties in Emotion Regulation Scale: mediator)
7. Working Alliance (Working Alliance Questionnaire: mediator)
8. Alexithymia (Toronto Alexithymia Scale: moderator)
9. Utilities (EuroQoL-5D: cost-utilities)
10. Health costs (Trimbos/iMTA questionnaire for costs associated with Psychiatric illness: cost utilities)

Completion date

31/01/2023

Eligibility

Key inclusion criteria
1. Age between 18 and 65 years
2. Meets DSM V criteria for autism spectrum disorder
3. Suicidal ideation above cutoff on SIDAS (score ≥21) and/or level of suicidality/self-harming behavior on the LPC rated as severe (score = 2 on any item)
4. Outpatient status

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
123

Key exclusion criteria
1. IQ <80
2. Addiction to illicit drugs in need of clinical detoxification
3. Insufficient mastery of the Dutch language

Date of first enrolment
23/08/2018

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Parnassia Psychiatric Institute
Zoutkeetsingel 40

The Hague
Netherlands
2512 HN

Study participating centre
Antes psychiatric institute
Maasstadweg 96
Rotterdam
Netherlands
3079 DZ

Study participating centre
Rivierduinen psychiatric institute
Sandifortdreef 17
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2333 ZZ

Study participating centre
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Sponsor information

Organisation
VU University

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Charity

Funder Name
Stichting tot Steun VCVGZ (Foundation for VCVGZ Support)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the trial participants have not provided consent to share this data with researchers outside the research group of this trial.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/04/2024	17/04/2024	Yes	No
Protocol article		17/03/2020	12/11/2020	Yes	No
Other publications	Cost-effectiveness	31/05/2025	03/06/2025	Yes	No